

Complementary medicines, clinical pharmacology and therapeutics

Complementary, or alternative medicines (CAM), describe a range of pharmaceutical-type products that includes herbal and traditional (mainly Chinese) medicines, homoeopathic remedies, essential oils and dietary supplements. They sit uncomfortably alongside the 'regular' chemical and biologically derived medicinal products that are the fruits of extensive research and development, and their classification is problematic.

The regulation of complementary medicines is also problematic; for example, some herbal medicines are licensed as such, some are exempt from licensing, and some are sold as food supplements. In some instances, the same herb is available in all three categories. This situation is largely historic—herbal products were granted a Product Licence of Right (PLR) when the licensing system was introduced in the 1970s because they were already on the market. Thus the evidence that manufacturers had to provide for proof of quality, efficacy and safety (largely for minor, self-limiting conditions) was taken from bibliography. Thus many licensed herbal medicines have not undergone the stringent testing of main-line pharmaceutical products.

Why should clinical pharmacologists have an interest in complementary medicines and in herbal products in particular? After all, one of the fundamental tenets of clinical pharmacology is the rigorous assessment of the mechanism of action of drugs, the efficacy, kinetics and safety using evidence from well-designed studies. Such evidence of efficacy, safety and quality, if it exists, for complementary medicines is perceived to be anecdotal, or empirical at best; rarely is it subjected to the rigorous prospective randomized controlled trial. It is easy to dismiss a serious consideration of complementary medicines. Yet there are at least three important reasons why clinical pharmacologists should give this branch of medicine more than a cursory glance.

First, CAMs are extensively used, and increasingly so. Retail sales of herbal products in the European Union in 1996 was estimated to be in the region of US\$7000 million. In the USA, herbal medicine annual retail sales

were estimated at US\$4 billion in 1998. In some European countries, notably Germany, the study of herbal medicine products is an established science and in the UK the systematic study of CAM is becoming established as a serious scientific endeavour.

Second, as patients are increasingly challenging the traditional paternalistic approach to therapy, many will be seeking advice from their general practitioners and hospital specialists on the use of alternative forms of therapy. In the year 2000 the House of Lords Select Committee published its report on CAM, recommending statutory regulation of certain types of complementary medicinal practitioners, including herbalists, and that regulatory bodies should develop guidelines on competence and training in CAM. In addition, the European Union has issued a draft Directive which aims to establish a harmonized legislative framework for authorizing the marketing of traditional herbal medicinal products.

Third, it is no longer acceptable to regard herbal medicines and traditional Chinese medicines as safe, simply because they lack robust evidence of efficacy. The recent safety concerns associated with the use of St John's Wort, Kava and Aristalochia bear this out. The mechanisms of the adverse events of these three herbal products fall within the sphere of interest of clinical pharmacologists, and particularly in the ever-burgeoning field of drug interactions. An obvious knock-on effect is that the teaching of clinical pharmacology, already stretched at undergraduate level, may have to include CAM.

It is therefore timely that the Journal should review the use and abuse of complementary medicines as well as continuing to attract original research papers based on efficacy and safety of individual products. The first of the two reviews, by Dr Jo Barnes, appears in this issue and we hope that it and its companion paper will stimulate interest and perhaps attract correspondence.

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Reviews Editor